

*Applicant: Phillips et al.
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Amendment and Response to Final Office Action dated June 3, 2003
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REMARKS

By this amendment, Applicants have amended Claims 1, 7 and 8 and added new Claims 46-57. Claims 11-20, 22-28, and 42-45 are cancelled without prejudice for prosecution in a divisional application. Claims 1-5, 7, 8, 10, and 46-57 are now pending in the above-identified patent application. No new matter is introduced in the amended Claims 1, 7 and 8, or in the new Claims 46-57 which are presented to address the final Office Action and to advance prosecution of the case. Reexamination and reconsideration of the application are requested in view of these amendments and the following remarks.

Claim Rejections under 35 U.S.C. §112, first paragraph

The Examiner maintains rejection of Claims 1-6 and 10 under 35 U.S.C. §112, first paragraph, for reasons of inadequate written description as previously set forth in the Office Action mailed December 17, 2002.

Claim 6 was previously cancelled in the response filed March 14, 2003 rendering moot rejection of this claim. Applicants request withdrawal of the rejection.

Applicants respectfully assert again that Claim 1 indicates the distinguishing attributes shared by the members of the claimed genus. The members of the genus claimed in Claim 1 are 2 to 20 base, 3'-OH, 5'-OH synthetic phosphodiester oligonucleotides. The members of the claimed genus also share the distinguishing feature of comprising GT-containing nucleotide sequences defined by $(G_xT_y)_n$, wherein x and y is an integer between 1 and 7, and n is an integer between 1 and 12. Another distinguishing feature is the ability to induce a response in an animal having cancer. These distinguishing features are described in the Specification on page 9, lines 17-24. Further, in Examples 4-37, the Specification provides a number of species of the claimed

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genus and describes the characteristics identifying the members of the genus. For example, the Specification states, on page 16, lines 5-6, that "Jurkat T cell proliferation was inhibited by the GT sequences tested, but not by the CT sequence tested", on page 26, lines 2-4, that "6 base GT-phosphodiester sequences inhibited Jurkat T, LNCaP and MCF-7 cell proliferation more effectively than 6 base GT-phosphorothioate sequences", and, on page 27, lines 4-7, that "substitution of a sulfur atom for a nonbridging oxygen atom on one or more phosphate groups of 6 base GT SEQ ID NO:25 resulted in a significant decrease in inhibition of Jurkat T and MCF-7 cell proliferation."

In addition to these statements asserted by Applicants in the response filed March 14, 2003 and included in this response, Applicants also respectfully assert that the specification provides numerous representative species to support the genus recited Claim 1. The sequences disclosed in the specification include over eighty 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 2, 3, 4, 5, 6, 7, 9, 11, 12, 14, 15, 18, 24, 33 and 45 bases in length.

Applicants respectfully assert that the disclosure provides sufficient description of the defining features of the claimed genus, and a representative number of species. In view of the foregoing, applicants respectfully request withdrawal of the rejection of Claims 1-6 and 10 under 35 U.S.C. §112, first paragraph.

Claim Rejections under 35 U.S.C. §102

The Examiner maintains rejection of Claims 1-3, 5, 7, and 8 under 35 U.S.C. §102(b) as anticipated by Frank *et al.* (International Patent Application PCT/EP96/02427) for reasons set forth in the Office Action of December 17, 2002.

Applicants respectfully assert that Frank *et al.* does not anticipate Applicants' compositions as claimed. Applicants' claimed compositions are all 3'-OH.

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5'-OH synthetic phosphodiester nucleotides. Applicants' have reviewed Frank *et al.* and do not find disclosure of 3'-OH, 5'-OH synthetic phosphodiester nucleotides. Accordingly, Frank *et al.* does not teach an element of Applicants' compositions as claimed, namely that they are 3'-OH, 5'-OH synthetic phosphodiester nucleotides. Applicants' claimed compositions are different chemical compositions of matter than those disclosed in Frank *et al.* Accordingly, since Applicants' claimed compositions are different chemical entities than those disclosed in Frank *et al.*, Applicants respectfully assert that Frank *et al.* does not anticipate Applicants' claimed compositions. In view of the foregoing, Applicants respectfully assert that Claims 1-3, 5, 7, and 8 are not anticipated by Frank *et al.* Applicants respectfully request withdrawal of the rejection.

Applicants also assert that Frank *et al.* does not teach a composition comprising the 3'-OH, 5'-OH synthetic phosphodiester oligonucleotide SEQ ID NO:45. Applicants respectfully bring to the Examiner's attention that oligonucleotide (or "sequence", as defined by the Specification on page 5, line 23) SEQ ID NO:45 is a 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. Frank *et al.* does not teach a 3'-OH, 5'-OH hexaoligonucleotide GGGAGG (see *Sequence Listing* in Frank *et al.*, pages 58-82). None of the oligonucleotides taught on page 17 of Frank *et al.* is the 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. Oligonucleotide Accession No. AAT80306 is a nine-base oligonucleotide HCV-186 CCCGGGAGG taught in Frank *et al.*, not 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG (SEQ ID NO:45).

Applicants also assert that Frank *et al.* is directed to compositions and methods of using these compositions for inhibiting the expression and replication of Hepatitis C virus. In contrast, Applicants' invention, as claimed, recites different compositions, namely 3'-OH, 5'-OH synthetic phosphodiester nucleotides, that are

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effective for treating cancer. Frank *et al.* does not teach 3'-OH, 5'-OH synthetic phosphodiester nucleotides, as claimed by Applicants.

In view of at least all the foregoing comments and reasons, Applicants respectfully assert that Claims 1-3, 5, 7, and 8 are not anticipated by Frank *et al.* Applicants request withdrawal of the rejection under 35 U.S.C. §102(b).

Applicants' note that Claim 4 was not rejected in view of Frank *et al.* New Claim 46 is based on Claim 4 and recites 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 2 to 7 bases in length. New Claim 47 recites 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequences of 6 bases in length. Applicants request favorable consideration of these claims and the claims that depend from them.

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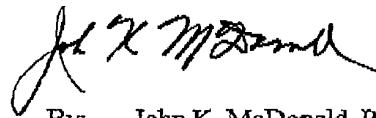
CONCLUSION

The foregoing is submitted as a full and complete response to the final Office Action mailed June 3, 2003, a two-month period of response to which expires on Monday, August 4, 2003.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 745-2470 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,



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